USER MANUAL

EASYMATE RESERVOIR

PM2300CE SERIES

SAVE THESE INSTRUCTIONS

⚠CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician.

PRECISION MEDICAL®

300 Held Drive
Northampton, PA 18067 USA

Tel: (+001) 610-262-6090
Fax: (+001) 610-262-6080

www.precisionmedical.com

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RECEIVING / INSPECTION

Remove the Precision Medical, Inc. EasyMate Reservoir from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your Liquid Oxygen Supplier.

INTENDED USE

The Precision Medical, Inc. EasyMate Reservoir is intended to provide a stationary storage source of liquid oxygen for Portable liquid oxygen systems and to provide supplemental USP oxygen to patients that may have difficulty extracting oxygen from the air that they breathe.

OPERATOR PROFILE

Supplemental oxygen patient that may have ambulatory capabilities requiring oxygen on a continuous basis.

READ ALL INSTRUCTIONS BEFORE USING

This manual instructs a user to operate the EasyMate Reservoir. This is provided for your safety and to prevent damage to the Reservoir. If you do not understand this manual, DO NOT USE the Reservoir and contact your Liquid Oxygen Supplier.

⚠ DANGER

Oxygen supplied from the Reservoir is for supplemental use and is not intended to be life-sustaining or life-supporting.

ABBREVIATIONS

DISS	Diameter Indexed Safety System
psig	Pounds Per Square Inch Gauge
lpm	Liters Per Minute
USP	United States Pharmacopeia
MAWP	Maximum Allowable Working Pressure
PH	Test Pressure

SAFETY INFORMATION - WARNINGS AND CAUTIONS

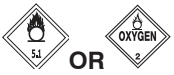
⚠ DANGER	Indicates an imminently hazardous situation which, if not avoided, will result in death or serious injury.
⚠ WARNING	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.
⚠ CAUTION	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.
CAUTION	Used without the safety alert symbol indicates a potentially hazardous situation which, if not avoided, may result in property damage.

CONSULT ACCOMPANYING DOCUMENTS

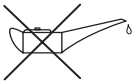
Symbol for “NO SMOKING”

Symbol for “Equipment MUST be kept in a well-ventilated area at all times.”

Symbol for “DO NOT touch Liquid Oxygen or parts that have been in contact with Liquid Oxygen.”



Symbol for “WARNING: HIGH PRESSURE OXIDIZING GAS VIGOROUSLY ACCELERATES COMBUSTION”



Symbol for “USE NO OIL”

Symbol for “PUSH to ACTIVATE”

Wipe Fill Connector dry

ALWAYS keep the Reservoir in an upright position

Maximum Flowrate is 8 Liters / Minute

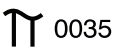
Volume, FULL

Volume, EMPTY

Mass

Examine; check

Symbol indicates the device complies with the requirements of Directive 93/42/EEC concerning medical devices and all applicable International Standards. **(On CE marked Devices ONLY)**



Symbol indicates the pressure vessel complies with the requirements of Directive 99/36/EC concerning transportable pressure equipment. **(On CE marked Devices ONLY)**

⚠WARNING

- This equipment is not intended for use by patients who would suffer immediate, permanent, or serious health consequences as a result of an interruption in the oxygen supply.
- **DO NOT** smoke in an area where oxygen is being used or stored.
- **DO NOT** disassemble or repair the Reservoir, this could create a hazardous condition or cause equipment failure. If you have problems, questions, or are unsure if equipment is operating properly, call your Liquid Oxygen Supplier.
- **DO NOT** use if dirt or contaminants are present on or around fill connectors on the Portable or Reservoir.
- **DO NOT** use oils, greases, lubricants or any combustible materials on or near the Reservoir. Wash hands properly prior to usage.
- **DO NOT** touch liquid oxygen or parts that have been in contact with liquid oxygen. Liquid oxygen is extremely cold (-297°F/-183°C). When touched, liquid oxygen, or parts of the equipment that have been carrying liquid oxygen, can freeze skin and body tissue.
- Fill the Reservoir with only Medical Grade Liquid Oxygen. USP applies in the United States.
- Before filling the Reservoir for the first time, Reservoir should be purged with oxygen.
- Verify that the fill connector of the Reservoir is compatible with the Reservoir being filled.
- Use only as prescribed by a physician.
- Consult with a transportation company when transporting the Reservoir by a public transportation system.

⚠WARNING

Keep equipment in a well-ventilated area at all times.

The Reservoir periodically releases small amounts of oxygen gas that must be ventilated to prevent buildup.

- **DO NOT** store liquid oxygen equipment in a closet, car / trunk, or other confined area.
- **DO NOT** place blankets, draperies, or other fabrics over equipment.

TO AVOID INCREASED RISK OF FIRE

- Keep the Reservoir away from electrical appliances. Use and store the Reservoir at least five feet from electrical appliances that may cause heat or sparks.
- **DO NOT** use near any type of flame or flammable/explosive substances. Use and store Reservoir at least five (5) feet away from equipment such as furnaces, water heaters, and stoves that may contain open flames.

⚠CAUTION

- The Reservoir contains magnetic, ferrous material that may affect the results of an MRI.
- ONLY use Precision Medical, Inc. Flowmeter (1MFA1883) or Dial Flowmeter (PM2300FCV-8).
- **DO NOT** autoclave.
- **DO NOT** gas sterilize.
- **DO NOT** clean with aromatic hydrocarbons.
- **DO NOT** immerse the Reservoir in any kind of liquid.
- Store the Reservoir in a clean area when not in use.
- Avoid dropping the Reservoir or placing it in a position where it could fall or be knocked over and become damaged.

SPECIFICATIONS

Dimensions:	**PM2345-0CE**		**PM2335-0CE**	
Diameter:	16 in	(40.6 cm)	16 in	(40.6 cm)
Height:	35 in	(88.9 cm)	31.6 in	(80.3 cm)
Weight:				
Full:	164.5 lbs	(74.6 kg)	133.3 lbs	(60.5 kg)
Empty:	51.2 lbs	(23.2 kg)	45.2 lbs	(20.5 kg)
Volume of Liquid Oxygen:	45 Liters		35 Liters	
Working Pressure:	18 –26 psi	(1.24 –1.79 bar)		
Maximum Allowable Working Pressure (MAWP):	26 psi	(1.79 bar)		

Operating Conditions:

Temperature: 0°F to 104°F (-17.7°C to 40°C)

Altitude: 500 ft (152 m) below Sea Level to 10,000 ft (3,048 m)

Storage Conditions:

Temperature: -40°F to 158°F (-40°C to 70°C)

Humidity: 95% Noncondensing

Oxygen DISS Outlet Connection:

Restricted to a maximum flow of 10 lpm ±1 lpm directly from outlet fitting.

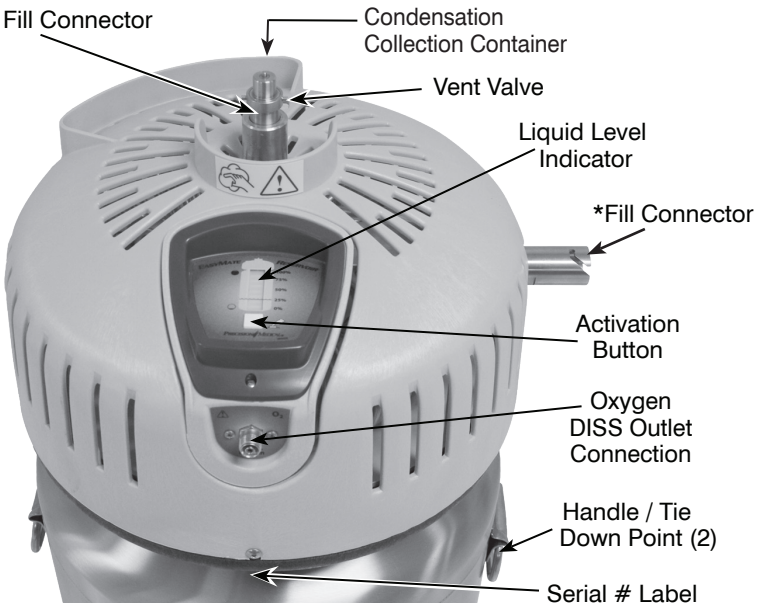
Maximum Usable Flow: 8 lpm

Specifications are subject to change without prior notice.

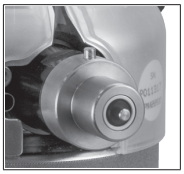
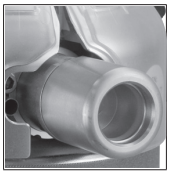
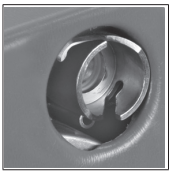
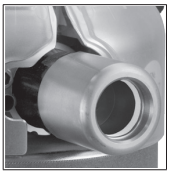
COMPONENT DESCRIPTION

⚠CAUTION

Missing or illegible labels must be replaced, contact Precision Medical, Inc.



FILL CONNECTOR

	*CAIRE	PB	PENOX	TAEMA
Portable:				
Reservoir:				

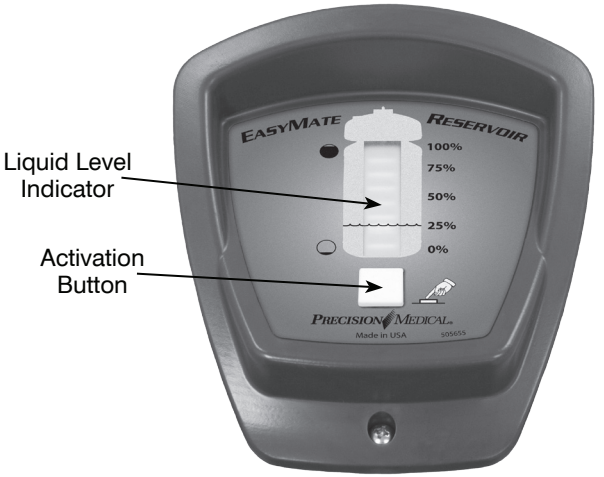
OPERATING INSTRUCTIONS

⚠WARNING

- Read this User Manual before operating the Reservoir.
- Before filling, to prevent freezing and possible equipment failure, use a clean dry cloth to wipe the fill connectors dry on the Reservoir and Portable.

EXTREME COLD HAZARD.

- **DO NOT** press or move the plastic poppet in the center of the fill connector on the Reservoir. This will cause a release of liquid oxygen from the fill connector.
- **DO NOT** leave the Liquid Oxygen System unattended during the filling operation.



To check the Liquid Oxygen Level:

Push the Activation Button on the Liquid Level Indicator. The lights will scroll from bottom to top, then the lights indicating the level of liquid oxygen will remain on for 5 seconds.

100% 75% 50% 25% 0%	*Each light represents approximately 12.5% of what the Reservoir is designed to contain.* **EXAMPLE:** This level sensor indicates that Reservoir is approximately 75% Full of Liquid Oxygen.
100% 75% 50% 25% 0%	When ONLY two (2) lights are illuminated, the Reservoir has 25% of Liquid Oxygen; ALMOST EMPTY. Contact your Liquid Oxygen Supplier to fill the Reservoir.
100% 75% 50% 25% 0%	• When ONLY the bottom light is flashing, indicates that the Reservoir is nearly empty; RESERVOIR NEEDS TO BE FILLED. • A flashing bottom light for a half second “ON” and a half second “OFF” for an eight (8) second duration, indicates the battery needs to be replaced.

⚠WARNING

If the Portable will not disengage easily, the Reservoir and the Portable may have become frozen together.

- **DO NOT USE FORCE**. Simply allow a few minutes for the frozen parts to warm, then disengage the Portable when the ice has melted.
- A ***MINOR*** LEAK is a trickle or a slight spray of Liquid oxygen coming from the Reservoir. The leaking may be stopped by reengaging and disengaging the Portable. If the leak persists, move the Reservoir to a well ventilated area if possible and call your Liquid Oxygen Supplier.
- A ***MAJOR*** LEAK is a steady stream of Liquid oxygen coming from the Reservoir. Ventilate the area by opening a window and/or door, if possible and stay away from the Reservoir. Call your Liquid Oxygen Supplier as soon as possible.

CAUTION

Inspect the Reservoir for visual damage before use, DO NOT USE if damaged.

To fill Portable:

1. Check the Liquid Oxygen level of the Reservoir.
2. Remove fill connector protective cap.
3. Use a clean dry cloth to wipe the fill connectors on the Portable and the Reservoir.
4. Follow the Portable User Manual for the filling instructions.
5. Carefully position the Portable, ensuring that the fill connector of the Portable aligns with the fill connector of the Reservoir.
6. Replace fill connector protective cap.

⚠WARNING

- If a liquid oxygen leak occurs at the fill connector when you disconnect the Portable, reconnect and disconnect the Portable to help dislodge any ice or other obstruction. If the liquid leak persists, notify your Liquid Oxygen Supplier.
- If you notice a steady stream of liquid oxygen at the fill connector when you disconnect the Portable, stay away from the device and immediately notify your Liquid Oxygen Supplier.
- **DO NOT** direct flow of oxygen at any person, or flammable material.
- Use ONLY a Flowmeter connected to the DISS outlet to breathe from the Reservoir.
- Using a Flowmeter other than the Precision Medical, Inc. EasyMate Reservoir Flowmeter will deliver lower than stated values.

BREATHING FROM THE RESERVOIR

Attach a Precision Medical, Inc. EasyMate Reservoir Flowmeter to the DISS outlet connection. The Precision Medical, Inc. EasyMate Reservoir Flowmeter is calibrated to function with the restrictor in the outlet fitting of the Reservoir.

NOTE: *Maximum Usable Flow: 8 lpm.*

BATTERY REPLACEMENT

When the Low Battery is indicated by the bottom light flashing rapidly on the Liquid Level Indicator, refer to section “To check the Liquid Oxygen Level” for complete instructions. For battery replacement call your Liquid Oxygen Supplier.

CLEANING / MAINTENANCE

⚠WARNING

- **DO NOT** allow water to enter any components, or Fill Connector.
- **DO NOT** immerse the Reservoir in any kind of liquid.
- **DO NOT** use any strong solvent or abrasive cleaners.
- **DO NOT** use alcohol, solvents, polishes, or any oily substance on Oxygen Equipment.

1. Clean exterior surfaces with a cloth dampened with mild detergent and water.
2. Wipe dry with a clean cloth prior to use.
3. Store Reservoir in a clean area free from grease, oil, and other sources of contamination.
4. Check and empty the Condensation Collection Container daily.
5. Clean the Condensation Collection Container with mild detergent and water, as necessary.

RETURNS

Returned products require a Returned Goods Authorization (RGA) Number, contact Precision Medical, Inc. All Reservoirs must be depleted of Liquid Oxygen prior to shipping and must be packaged in sealed containers to prevent damage. Precision Medical, Inc. will not be responsible for goods damaged in transit. Refer to Precision Medical, Inc. Return Policy available on the Internet, www.precisionmedical.com.

Manuals available on our Website; www.precisionmedical.com.

DISPOSAL INSTRUCTIONS

Dispose of the Reservoir in accordance with the local regulations.

Please Recycle

TROUBLESHOOTING

If the Reservoir fails to function, consult the Troubleshooting Guide below.
If problem cannot be solved, consult your Liquid Oxygen Supplier.

PROBLEM	PROBABLE CAUSE	REMEDY
Portable will not fill	1. Not connecting the Fill Connectors completely 2. Reservoir empty	1. Make sure the Fill Connectors are fully engaged 2. Contact Liquid Oxygen Supplier to refill Reservoir
Unable to disconnect the Portable from Reservoir	Fill connectors frozen from moisture on the Fill Connectors	Allow time for the Fill Connectors to thaw
Bottom light flashes rapidly	Low Battery	Call your Liquid Oxygen Supplier for battery replacement
No light(s) will show on the Liquid Level Indicator	Dead battery	Call your Liquid Oxygen Supplier for battery replacement
Water leaking from Reservoir	Condensation Container is full	Empty the Condensation Container
***MINOR LEAK* of Liquid Oxygen** (Ref page 7)	Frost in the Fill Connector	Disconnect and reconnect Portable
***MAJOR LEAK* of Liquid Oxygen** (Ref page 7)	Equipment Failure	Call your Liquid Oxygen Supplier

ACCESSORIES / REPLACEMENT PARTS

DESCRIPTION	PART #
Flowmeter, 0-8 lpm	1MFA1883
Dial Flowmeter, 0-8 lpm	PM2300FCV-8
Condensation Collection Container	505660
Roller Base	505382
PB Protective Cap Assembly	507027

RESERVOIR FILL PROCEDURE

"For Liquid Oxygen Supplier ONLY"

- Refer to all applicable governing standards for handling, storing, transporting and filling of liquid oxygen systems.
- For recommended testing of the Reservoir, refer to www.precisionmedical.com under the "Forms and Notices" section.
- This fill procedure will help the Liquid Oxygen Supplier fill the Reservoir in a safe and efficient manner.

a) Liquid oxygen source requirements

The Reservoir must only be filled with Medical Grade Liquid Oxygen. The saturation pressure should be a minimum of 23 psig (1.59 bar) to ensure proper operation and prevent any delay in use. In order to achieve the saturation pressure of the Reservoir, the saturation pressure of the LOX fill source must be considered. The fill source saturation pressure requirement depends on the type of filling technique used. The most common technique "Standard Fill" uses a fill source with a saturation pressure of 40 - 50 psig (2.76 - 3.45 bar). The less common technique is the "Fast Fill" that requires a LOX saturation pressure of 20 - 22 psig (1.38 - 1.52 bar). In this case the fill source must have a pressure building system so that head pressure in the fill source can be raised in order to transfer the LOX into the Reservoir.

b) Required Equipment

Liquid Oxygen source
Liquid Oxygen transfer line
Vent-to-Fill key (P/N 505400)
Pressure Gauge, 0 - 30 psig (0 - 2.07 bar), (P/N 505648)

c) Pre-Fill Inspection

Perform the following visual inspection of the Reservoir and determine its operational status before filling. Correct any problems before filling the Reservoir.

1. Ask the patient (when applicable) if there are any questions or concerns regarding the equipment since the last fill.
2. Visually inspect the Reservoir for damage or missing components.
3. Verify that the following labels are present and legible:
    1) Fill Connector label
    2) Liquid Level Indicator label
    3) Outlet Connection label
    4) Warning label
    5) Serial Number label
4. Verify that no frost or heavy condensation is present on the container below the plastic shroud.
5. Verify that the Liquid Level Indicator is consistent with the delivery schedule and expected patient usage. Verify the Liquid Level Indicator is functioning when activated.

NOTE: A flashing bottom light for a half second “ON” and a half second “OFF” for an eight (8) second duration, indicates the battery needs to be replaced.

6. Verify that the Fill Connector is not worn, leaking, or damaged.
   NOTE: Ensure that the Protective Cap for the fill connector is not damaged.
7. Verify that the slots on the Vent Valve are not bent or broken.
8. Verify that the Condensation Collection Container is in place and empty.

d) Fill Procedure

⚠DANGER

Explosive hazard. Extreme high pressure can rupture a transfer line. Make sure the specified pressure relief valve is present, in the proper location, and functioning properly on the transfer line assembly.

⚠WARNING

- **Fire hazard.** Liquid oxygen spilled on asphalt or any other combustible surface will increase the possibility of fire if an ignition source is present. ALWAYS fill the unit on a noncombustible surface, such as concrete or a steel drip pan.
- **Fire hazard.** Liquid oxygen spillage will occur if the Reservoir is tipped over. Before transporting, secure the Reservoir containing liquid oxygen in an upright position.
- **Fire hazard.** Oxygen can accumulate in a delivery vehicle. Exhaust vent gases to outside of vehicle.

1. Wear proper protective clothing during the fill process.
2. For the fill method being used, verify the proper saturation pressure of the fill source per section (a) “Liquid oxygen source requirements”.
3. Attach one (1) end of the transfer line source adapter to the liquid withdrawal valve of the source tank. Position the source adapter relief valve straight up.
4. Attach a 0 - 30 psig (0 - 2.07 bar) pressure gauge to the Reservoir Oxygen Diss Outlet Connection. If the Reservoir contains some liquid oxygen, verify that the Reservoir pressure gauge reads in the range of 18 - 26 psig (1.24 - 1.79 bar). If pressure exceeds 28 psig (1.93 bar), service is required. DO NOT fill the Reservoir.
5. Remove fill connector Protective cap from fill connector on the Reservoir. Check the fill connectors on both the Reservoir and the fill adapter to ensure that they are clean and dry. Wipe the connectors with a clean, lint-free cloth or blow-dry with gaseous oxygen or nitrogen as needed.
6. Using the Vent-to-fill key, open the Vent Valve on the Reservoir by rotating the tool a ¼ turn counterclockwise.
   NOTE: At this point you may hear a venting noise if the Reservoir unit is pressurized.
7. Engage the transfer line to the Fill Connector on the Reservoir by aligning the fill connector on the transfer line directly over the Fill Connector on the Reservoir, and apply downward force.
8. Maintain a downward force on the transfer line fill adapter while slowly opening the liquid valve on the source tank. At this point a vigorous audible venting noise will confirm that the filling process has begun. Adjust the source tank liquid valve as needed to maintain pressure gauge at 20 - 22 psig (1.38 - 1.52 bar) during the fill.

NOTE: • It may be necessary to open the source tank liquid valve completely and partially close the Reservoir vent valve to maintain the proper pressure throughout the fill.

• As the level of liquid oxygen nears the top of the Reservoir inner container, the sound and appearance of vapors escaping through the Vent Valve will change. The vapor will become denser, and as liquid oxygen reaches the Vent Valve, a discharge of liquid oxygen will be visible and audible.

⚠WARNING

Extreme cold hazard. Liquid oxygen discharge from the Fill Connector can occur. When disconnecting the transfer line, never stand directly over the Reservoir Fill Connector. If the Reservoir Fill Connector stays open and minor liquid oxygen discharge occurs, carefully engage and disengage the transfer line to help dislodge any ice or other obstruction. If major liquid oxygen discharge (steady stream) occurs, open the Vent Valve (if safely possible) to vent pressure and stop the release of liquid oxygen. Open windows and doors to ventilate the room and do not walk on areas exposed to liquid oxygen for 60 minutes after frost disappears.

9. When you observe the first steady discharge (greater than 1 second) of liquid oxygen from the Vent Valve, close the Vent Valve and disconnect the transfer line from the Reservoir by lifting the fill adapter straight up. If the transfer line will not disengage close the liquid valve on the source tank and allow the transfer line and fill connectors to thaw.

⚠CAUTION

If the Vent Valve freezes in the open position, terminate the fill by disconnecting the transfer line and then allow the vent valve to warm until it closes easily. If the vent valve remains open for a period of time, the liquid oxygen in the unit will de-saturate to a pressure lower than required.

10. Close the source tank liquid valve when the frost melts from the transfer line assembly.

e) Post-Fill Inspection

Perform the following procedure to inspect the Reservoir and determine its operational status after filling it with liquid oxygen. Correct observed problems before placing the unit in service.

1. Verify that the Reservoir Fill Connector is closed and not leaking.
2. Verify that the Vent Valve is completely closed and not leaking.
3. Verify that the pressure gauge attached to the Reservoir Oxygen DISS Outlet Connection reads equal or greater than 20 psig (1.38 bar) within five minutes after terminating the fill.
4. Verify that there is no frost or heavy condensation on the container below the plastic shroud.
5. Verify that all lights are illuminated when the Liquid Level Indicator button is activated.
6. Disconnect the pressure gauge from the Reservoir Oxygen DISS Outlet Connection.

f) Checking Saturation Pressure

Perform the following procedure as needed to determine the saturation pressure of the liquid oxygen in the Reservoir.

1. Attach a 0 - 30 psig, (0 - 2.07 bar) pressure gauge to the Reservoir Oxygen DISS Outlet Connection. Note the pressure indicated on the gauge.
2. Momentarily open the Vent Valve on the Reservoir and observe the pressure gauge pointer as it drops.
3. Note the pressure value where the gauge drops the lowest and then close the Vent Valve. This is the approximate saturation pressure of the Reservoir. Saturation pressure readings between 18 and 26 psig (1.24 - 1.79 bar) are in the acceptable pressure range of the unit.

LIMITED WARRANTY
AND
LIMITATION OF LIABILITY

Precision Medical, Inc. warrants that the Precision Medical EasyMate Reservoir (the Product) and the following component parts thereof will be free of defects in workmanship and/or material for the following period:

EasyMate Reservoir	One (1) year from date of shipment
Vessel Vacuum	Five (5) years from date of shipment

This limited warranty does not cover:

1) Normal routine service items,
2) Defects due to the wear and tear caused by mating components
3) Repair or replacement necessitated by misuse, abuse, or accident.

Replacement parts or repaired products shall be free from defects in workmanship and materials for the duration of the unexpired portion of the original warranty or ninety (90) days from the date of reshipment, whichever is longer.

Should any failure to conform to this warranty appear within the applicable period, Precision Medical, Inc. shall, upon written notification thereof and substantiation that the goods have been stored, installed, maintained and operated in accordance with Precision Medical, Inc.'s instructions, operational verification procedure, which is included in the Service Manual and standard industry practice, and that no modifications, substitutions, or alterations have been made to the goods, shall, in its discretion, and at its own expense, repair or replace the defective component(s).

ORAL STATEMENTS DO NOT CONSTITUTE WARRANTIES AND THERE ARE NO WARRANTIES OTHER THAN AS SET FORTH IN THIS CONTRACT. Neither the representative of Precision Medical, Inc. nor any retailers are authorized to make oral warranties about the merchandise described in this contract, and any such statements shall not be relied upon and are not part of the contract for sale. This writing is a final, complete and exclusive statement of the terms of the contract and sale.

Precision Medical, Inc. Disclaims any warranty of merchantability, fitness for a particular purpose or any other warranty of quality, whether express or implied except as set forth above.

Precision Medical, Inc. Shall not under any circumstances be liable for special, incidental or consequential damages including but not limited to lost profits, lost sales, or injury to person or property. Correction of non-conformities as provided above shall constitute fulfillment of all liabilities of Precision Medical, Inc. Whether based on contract, negligence, strict tort or otherwise. Precision Medical, Inc. Reserves the right to discontinue manufacture of any product or change product materials, designs, or specifications without notice.

Precision Medical, Inc. reserves the right to correct clerical or typographical errors without penalty.

DECLARATION OF CONFORMITY

Manufacturer:	Precision Medical, Inc. 300 Held Drive, Northampton, PA 18067, USA CONTACT: Quality Manager Phone: 610-262-6090
Authorized European Representative:	Emergo Europe (European Office) Molenstraat 15 2513 BH, The Hague The Netherlands Phone: +31 (0) 70.345.8570 Fax: +31 (0) 70.346.7299
Product:	EasyMate Reservoir
Model(s):	PM2335 (CE), PM2345 (CE) Series
MDD Class:	IIb
Classification criteria:	Clause 3.2 Rule 11 of Annex IX of MDD

As delivered, the object of the declaration described above is in conformity with the requirements of MDD 93/42/EEC Annex II.3, Directive 2007/47/EC Of The European Parliament And Of The Council, 99/36/EC Transportable Pressure Equipment Directive 1999 and the following documents:

BS EN 1251-1, BS EN 1251-2, BS EN 1251-3, BS EN 1418, BS EN 1626, BS EN 1797-1, BS EN 12300, BS EN 60601-1-6, BS EN 60601-1-2, BS EN ISO 18777, BS EN ISO 15614-1, EN 980, EN 1041, ISO 14971, ISO 15001, ISO 7000

Notified Body for Product Safety: TUV Rheinland Products Safety GmbH CE 0197

Certification Registration No's: HD 60019110 0001

Notified Body for Pressure Equipment: TUV Rheinland Pressure Equipment GmbH 0035

Certification Registration No's: 01 202 USA-U-10-4086-T

PRECISION MEDICAL®

ISO 13485 Certified

Precision Medical, Inc.
300 Held Drive
Northampton, PA 18067 USA

(+001) 610-262-6090

(+001) 610-262-6080

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505129EN Rev1 03/18/11 PRINTED IN USA